K04 1990

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FUJIFILM MEDICAL SYSTEMS USA, INC.
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510(K) Summary

In accordance with the requirements of the Safe Medical Device Act, FUJIFILM Medical Systems, USA, Inc. herewith submits a 510(K) summary of safety and effectiveness for the following device.

SUBMITTER NAME / ADDRESS:	FUJIFILM Medical Systems, USA, Inc. 419 West Avenue Stamford, CT 06902
CONTACT PERSON / TEL NO:	Frank Gianelli Regulatory Coordinator
DATE SUMMARY PREPARED:	June 11, 2004
ESTABLISHMENT NO.:	2443168
TRADE/PROPRIETARY NAME:	Fuji Medical CR Console, Flash IIP
COMMON/USUAL NAME:	Medical Image Processing Workstation
CLASSIFICATION NAME:	Picture archiving and communications system
CLASS/PANEL:	Class II, 90-LLZ, 21CFR 892.2050
PREDICATE DEVICE(S):	Fuji CR DMS CRT Image Console HI-C654 (for networks)

DEVICE DESCRIPTION:

The CR Console (Flash IIP) is used by a radiographer to view CR images for final quality assurance (QA) checking and image processing/optimization prior to transfer of those images to external devices such as a PACS or a printer. Furthermore, when connected to Fuji Image Readers via a network, the CR Console is used to enter patient ID information, exposure information and register Image Plate (IP) barcode numbers. The CR Console application software runs on an "off-the-shelf" personnel computer under the Windows 2000 or Windows XP operating system with a choice of a high resolution monitor (Plus configuration) or standard resolution monitor (Lite configuration) for image display.

INTENDED USE:

The Fuji CR Console (Flash IIP) is a CR modality workstation intended to associate FCR images (except mammography images) with patient and exam information, apply image processing to facilitate diagnosis, display the image, and output the resulting image and exam data for further display, distribution, or archiving.

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TECHNOLOGICAL CHARACTERISTICS:

Fuji CR Console (Flash IIP) is considered comparable and substantially equivalent to the Fuji CR DMS CRT Image Console HI-C654 manufactured by Fuji.

Feature	CR Console Plus (Flash Plus IIP)	CR Console Lite (Flash Lite IIP)	Fuji HI-C654
Minimum Basic Computer Configuration	Computer "Off the Shelf" • Desktop or Tower • CPU: Pentium 4 • Bus: ISA/PCI • RAM: 512MB • Hard Drive: 40 GByte • Floppy Drive: 3½" • CD-ROM • Keyboard • Mouse • Barcode scanner	Computer "Off the Shelf" • Desktop or Tower • CPU: Pentium 4 • Bus: ISA/PCI • RAM: 512MB • Hard Drive: 40 GByte • Floppy Drive: 3½" • CD-ROM • Keyboard • Mouse • Barcode scanner	Computer (custom design): • Desktop • CPU: 68020 • Bus: Fuji-Bus • RAM: 5MB • Hard Drive: 4 Gbyte • Floppy Drive: 3½" • Keyboard • Mouse
Operating System Software	Microsoft Windows 2000 or Windows XP	Microsoft Windows 2000 or Windows XP	proprietary
Ethernet Capability & Type	Yes: LAN	Yes: LAN	Yes: LAN
Image Transfer	via DICOM 3.0 & via Fuji DMS Network	via DICOM 3.0 & via Fuji DMS Network	via Fuji DMS network
Image Display	19" Monochrome 2MP LCD with Touch screen	15" color 1MP LCD with Touch screen	20" 1MP Monochrome CRT
Fuji Image processing functions	Yes, enhanced	Yes, enhanced	Yes
Image viewing & orientation functions	Yes, enhanced	Yes	Yes
Connects to Fuji CR Image Readers	Yes	Yes	Yes
Connects to Fuji Image Recorders (Printers)	Yes	Yes	Yes

SAFETY INFORMATION:

Fuji CR Console (Flash IIP) introduces no new safety and efficacy issues other than those already identified with the predicate device. The results of a hazard analysis, combined with the appropriate preventive measures taken indicate that the device is of minor level of concern as per the May 29, 1998 issue of the "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices".

Fuji CR Console (Flash IIP) comply with the following mandatory and voluntary standards:

- Information Technology Equipment Part 1: General Requirements for Safety UL Standard 60950
- Information Technology Equipment, Radio Disturbance (Emissions) Characteristics-Limits and Methods of Measurements, IEC/CISPR 22 (EN55022)
- Information Technology Equipment, Immunity Characteristics-Limits and Methods of Measurement, IEC/CISPR 24 (EN55024)
- DICOM (Digital Imaging and Communications in Medicine) - Developed by the American College of Radiology and the National Electrical Manufacturers Association.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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FUJIFILM Medical Systems USA, Inc.
% Mr. William J. Sammons
Project Engineer
Underwriters Laboratories, Inc.
Research Triangle Park Division
12 Laboratory Drive
P.O. Box 13995
Research Triangle Park, NC 27709-3995

Re: K041990
Trade/Device Name: Fuji Medical CR Console, Model Flash IIP
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: July 20, 2004
Received: July 23, 2004

Dear Mr. Sammons:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications For Use

510(k) Number (if known): K041990

Device Name: **Fuji CR Console (Flash IIP)**

Indications For Use:

The Fuji CR Console is a CR modality workstation intended to associate FCR images (except mammography images) with patient and exam information, apply image processing to facilitate diagnosis, display the image, and output the resulting image and exam data for further display, distribution, or archiving.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K041990